

REMARKS

Claims 11, 21, 22, and 24-40 were pending in the application. Claim 40 has been cancelled without prejudice to presentation in future related applications. Claims 11, 22, 34, and 39 have been amended for further grammatical clarity and to recite an active step of diagnosing colon, breast or prostate cancer in a patient. Claim 39 also has been amended to clarify that the polynucleotide hybridizes to the complement of the recited nucleic acid and to recite hybridization conditions. Support for the amendment to claim 39 can be found, for example, at paragraph [0054]. Unless otherwise indicated, paragraph numbering is based on Publication No. US 2002/0182856A1, which corresponds to the above-referenced application. No new matter has been added.

Upon entry of this amendment, claims 11, 21, 22, and 24-39 will be pending. Applicant respectfully requests reconsideration and allowance of claims 11, 21, 22, and 24-39 in view of the above amendments and following remarks.

Withdrawal of Previous Rejections

Applicants acknowledge with appreciation the withdrawal of the following:

- a) rejection of claims 11, 21, 22, and 24-38 under 35 U.S.C. §112, first paragraph, for lack of enablement;
- b) rejection of claims 11 and 34-38 under 35 U.S.C. §112, first paragraph, for lack of written description;
- c) rejection of claims 11, 21, and 24-38 under 35 U.S.C. §112, second paragraph, as being indefinite; and
- d) rejection of claims 11, 21, 22, and 24-38 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2006/0194265.

Information Disclosure Statements

The Office requested that Applicants note the date of publication for references AA, AH, AI and AJ. Each of these references was published online on August 19, 2002.

Applicants also note that initialed PTO-1449 forms have not been received from the Supplemental Information Disclosure Statements filed on August 18, 2004, and March 5, 2008 (copies enclosed). Applicants request consideration of these references and return of the initialed PTO-1449 forms in the next communication from the Patent Office.

Rejection under 35 U.S.C. §112, first paragraph

The Office rejected claims 11, 21, 22, and 24-40 under 35 U.S.C. §112, first paragraph, for allegedly containing new matter. The Office asserted that the method wherein the level of expression is increased and indicates a particular cancer is not set forth in the specification. The Office further asserted that “there seems to be insufficient disclosure for SEQ ID NO:1175 is regulated in any particular cancer, see page 26.” Applicants disagree.

The subject matter of a claim need not be described literally in order for the disclosure to satisfy the description requirement. See, for example, §2163.02 of the MPEP. Rather, claim limitations must be supported expressly, implicitly, or inherently in the originally filed disclosure. The specification indicates that the sequence set forth in SEQ ID NO:1175 is a CA sequence. The specification at paragraph [0008] indicates that CA genes are differentially expressed in breast and prostate cells compared to other cells. Paragraph [0018] indicates that CA sequences can be associated with breast cancer or prostate cancer. Paragraph [0021] indicates that prostate cancer can be diagnosed. The specification also indicates at paragraph [0033] that CA sequences can be up-regulated in carcinoma tissue. Accordingly, the specification provides sufficient support for claims 11, 21, 22, and 24-40, which refer to colon, breast, or prostate cancer and increases in expression. The Office is requested to withdraw the rejection of claims 11, 21, 22, and 24-40 under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §112, second paragraph

The Office rejected claim 39 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office asserted that claim 22 was indefinite in the recitation “hybridizes under highly stringent conditions.”

Amended claim 39 recites that hybridization is performed at 50°C to 60°C in 5 X SSC (9 mM saline /0.9 mM sodium citrate) and is sufficiently definite. The Office is requested to withdraw the rejection under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §102(e)

The Office rejected claims 11, 21, 22, and 24-38 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2004/0038207 (the '8207 publication). The Office asserted that "given the sialophorin is the same as that claimed and the patient sample listed in the claims is not limited, as well as the active method steps are the same, the prior art reads on detection of colon, breast, and prostate cancer.

Amended independent claims 11, 22, 34, and 39 recite an active step of diagnosing cancer based on an increase in the expression product in a patient's colon, breast, or prostate tissue sample. The '8207 publication does not disclose that cancer can be diagnosed based on an increase between the level of the expression product in the patient's colon, breast, or prostate tissue sample and a control sample. Rather, the '8207 publication discloses that expression patterns of genes can be used to characterize bladder cancer. Accordingly, the '8207 publication does not anticipate claims 11, 21, 22, and 24-38. The Office is requested to withdraw the rejection under §102(e) over the '8207 publication.

CONCLUSION

It is believed that any pending objections and rejections have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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Applicants submit that claims 11, 21, 22, and 24-39 are in condition for allowance, which action is requested. Please apply the one-month Petition for Extension of Time fee and any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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